DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 17 1988

Re: Naftin
Docket No. 88E-0183

SOLICITOR

#13

The Honorable Donald J. Quigg
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

JUN 22 1988

U.S. PATENT & TRADEMARK OFFICE

Dear Commissioner Quigg:

This is in regard to the application for patent extension for U.S. Patent No. 4,282,251, filed by Sandoz Pharmaceutical, Inc, under 35 U.S.C. et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Naftin, the human drug product claimed by the patent.

The total length of the review period for Naftin is 2,903 days. Of this time, 2,189 occurred during the testing phase and 714 occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 21, 1980. The applicant claims January 17, 1980 as the effective date of the first investigational new drug application (IND) related to the approved product. However, FDA records indicate that the first IND became effective on March 21, 1980, when IND 17-148 was removed from clinical hold.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: March 18, 1986. The applicant claims that the new drug application for the product (NDA 19-599) was initially submitted on March 14, 1986. However, FDA records indicate that NDA 19-599 was received on March 18, 1986.

3. The date the application was approved: February 29, 1988. FDA has verified the applicant's claim that NDA 19-599 was approved on February 29, 1988.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Gerald D. Sharkin
Patent and Trademark Affairs
Sandoz Pharmaceuticals
59 Route 10
E. Hanover, N.J. 07936